Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jul 2026

Evaluation of the effectiveness of high flow nasal cannula (HFNC) oxygen delivery in comparison with non-invasive ventilation (NIV) in patients with COVID-19

Protocol summary

Study aim

Evaluation of the effectiveness of using high flow nasal cannula oxygen delivery method (HFNC) in comparison with non-invasive ventilation (NIV) in patients with COVID-19

Design

The present study is a clinical trial with two intervention groups, with parallel and double-blind groups, randomized with a sample size of 60 patients.

Settings and conduct

This study is performed as a clinical trial in patients with covid-19 referred to the corona ward of Masih Daneshvari Hospital in Tehran who need to be hospitalized and receive respiratory support. The collected data are real and experimental. Based on the objectives and hypotheses of this study, the clinical conditions and important parameters obtained from arterial blood gas analysis of patients after treatment with high flow nasal cannula oxygen delivery and non-invasive ventilation will be examined. Simple randomization is done using codes assigned to each patient and based on the file number. Patients with an even code are in the high-flow oxygen delivery group, and patients with an odd code are in the non-invasive ventilation group. To treat any possible complications, the care provider is not blind. Other blind groups are as below: Participants and data analyzer researcher

Participants/Inclusion and exclusion criteria

Inclusion criteria: oxygen saturation less than 90%, Signing a written consent to participate in the study, Age over 18 years Exclusion criteria: Acute or chronic pulmonary or renal failure, pregnancy or breastfeeding, acute heart failure

Intervention groups

Patients with COVID-19 disease who require hospitalization and respiratory support are divided into two groups. In the first group, patients receive oxygenation through a high-flow nasal cannula, and in the second group, patients receive non-invasive ventilation.

Main outcome variables

Arterial blood gas analysis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160516027929N8**
Registration date: **2021-03-02, 1399/12/12**
Registration timing: **retrospective**

Last update: **2021-03-02, 1399/12/12**
Update count: **0**

Registration date

2021-03-02, 1399/12/12

Registrant information

Name

Atefeh Fakharian

Name of organization / entity

National research institute of tuberculosis and lung diseases

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date
2020-11-21, 1399/09/01
Actual recruitment start date
2020-06-21, 1399/04/01
Actual recruitment end date
2020-11-21, 1399/09/01
Trial completion date
2020-11-21, 1399/09/01

Scientific title
Evaluation of the effectiveness of high flow nasal cannula (HFNC) oxygen delivery in comparison with non-invasive ventilation (NIV) in patients with COVID-19

Public title
Evaluation of the effectiveness of high flow oxygen delivery through the nasal cannula in comparison with non-invasive ventilation in patients with COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Arterial blood oxygen saturation less than 90% Signing a written consent to participate in the study Age over 18 years
Exclusion criteria:
Pulmonary insufficiency Acute or chronic renal failure Pregnancy or breastfeeding Acute heart failure
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
With simple randomization and using a random number table and individual randomization unit. To randomize, we use a table consisting of random digits 0 to 9. Each digit of this table is repeated the same on average. There is no pattern of recognizable numbers. In this method, each number is assigned to a treatment group. We start from the first line of the table and move down line by line. For the two treatments, we put the numbers 0 to 4 for treatment A and the numbers 5 to 9 for treatment B. The numbers in the first line of the table are as follows: 0,5,2,7,8,4,3,7,4,1,6,8,3,8,5,1,5,6,9,6, ... Now for people based on the above numbers, we have the following allocation: A, B, A, B, B,... We will continue the above process until the two groups are completed.
Blinding (investigator's opinion)
Single blinded
Blinding description
To prevent any possible complications, the primary caregiver is aware of the allocation of treatment groups. Patients in the study were also not blinded to the treatment they were receiving. Researchers responsible for data collection and analysis are not aware of the allocation of different study groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Science
Street address
Masih Daneshvari Hospital, Darabad, Shahid Bahonar St. (Niavaran)
City
Tehran
Province
Tehran
Postal code
1956944413
Approval date
2021-01-11, 1399/10/22
Ethics committee reference number
IR.SBMU.NRITLD.REC.1399.210

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
B34.2
ICD-10 code description
Coronavirus infection, unspecified

Primary outcomes

1

Description
partial pressure of carbon dioxide
Timepoint
Before the intervention, 24 hours after the intervention and 48 hours after the intervention
Method of measurement
Through blood sampling and blood gas analysis

Secondary outcomes

1

Description
oxygen saturation
Timepoint
Before the intervention, 24 hours after the intervention and 48 hours after the intervention
Method of measurement
Through blood sampling and blood gas analysis

Intervention groups

1

Description
Intervention group: Before starting oxygen therapy, patients undergo treatment approved by the Ministry of Health. Oxygen therapy of patients is performed during the period of receiving Remdesivir. Before starting oxygen therapy, clinical examination and analysis of arterial blood gases in these patients will be on the agenda. Oxygen delivery to the patient with the high flow nasal cannula is then done (a device with Fisher & Paykel model) for 24 hours. Flow and temperature are adjusted according to the patient's satisfactory breathing. After 24 hours and in the next stage, 48 hours after the start of oxygenation, patients' clinical manifestations and ABG results will be evaluated.
Category
Treatment - Devices

2

Description
Intervention group: In the second group, as in the first group, patients undergo treatment approved by the Ministry of Health. During the period of receiving Remdesivir, non-invasive ventilation is on the agenda. Before starting oxygen therapy, the clinical condition and arterial blood gas analysis of these patients will be reviewed.24 hours after non-invasive ventilation and in the next stage, 48 hours after the onset of oxygenation, clinical symptomes and ABG results of patients will be evaluated.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Atefeh Fakharian
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Masih Daneshvari Hospital, Darabad, Shahid Bahonar St. (Niavaran), Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr. Afshin Zarghi
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Atefeh Fakharian
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Pulmonology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more informationn
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available